

September 13, 2001

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204

RE:

Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that PhytoPharmica at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

COMPANY	PRODUCT NAME	<u>DIETARY</u> INGREDIENTS	<u>STATEMENTS</u>
Phyto- Pharmica (a Division of Integrative Therapeutics Inc.)	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	Dietary Supplement to relieve occasional heartburn, acid indigestion, & upset stomach*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

Title: Senior Vice President of Scientific Affairs

anene moenchnere

Date: 9-13-01

If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely,

Jeanene Moenckmeier

Director of Legal Affairs

975 0162 LFT 86/0

825 CHALLENGER DRIVE GREEN BAY, WI 54311-8328 920-469-9099

TOLL FREE 800-553-2370 Fax 920-469-4418

FAX TOLL FREE 888-311-5657 WWW.PHYTOPHARMICA.COM

HFlp



September 14, 2001

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204

Label Claims/Disclaimers

,

Dear Sir/Madam:

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This letter is to notify you that PhytoPharmica at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Phyto- Pharmica (a Division of Integrative Therapeutics Inc.	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	Heartburn Free will not reduce mineral absorption or inhibit protein digestion*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: Kull. D.t.
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 9-14-01

If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely, Janene Moenchmeier

Jeanene Moenckmeier Director of Legal Affairs

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September 18, 2001

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204

RE:

Label Claims/Disclaimers

Dear Sir/Madam:

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COMPANY	PRODUCT NAME	<u>DIETARY</u> INGREDIENTS	<u>STATEMENTS</u>
Phyto- Pharmica (a Division of Integrative Therapeutics Inc.	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	Does not interfere with protein digestion or mineral absorption*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: Lulli U.t.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Lanene Moenchmeier

Date: 9-18-51

If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely,

Jeanene Moenckmeier
Director of Legal Affairs

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September 19, 2001

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204

RE:

Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that PhytoPharmica at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Phyto- Pharmica (a Division of Integrative Therapeutics Inc.)	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	Heartburn Free does not shut down acid production nor adversely affect acid- producing cells.*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Janene Moenchneier

If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely,

Jeanene Moenckmeier

Director of Legal Affairs

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September 20, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

RE:

Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that PhytoPharmica at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

COMPANY	PRODUCT NAME	<u>DIETARY</u> INGREDIENTS	<u>STATEMENTS</u>
Phyto- Pharmica (a Division of Integrative Therapeutics Inc.)	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	Does not disrupt stomach acids, allowing proper digestion.*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: Kill . Wit

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

lanene moenchmerer

Date: 9-20-01

If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely,

Jeanene Moenckmeier Director of Legal Affairs

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